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NOTICE OF ALLOWANCE AND FEE(S) DUE

33401 7590 03/12/2009 MCDERMOTT WILL & EMERY LLP 2049 CENTURY PARK EAST 38th Floor LOS ANGELES, CA 90067-3208

| EXAMINER | | | | | |
|---------------|--------------|--|--|--|--|
| TOTH, KAREN E | | | | | |
| ART UNIT | PAPER NUMBER | | | | |
| 3735 | • | | | | |

DATE MAILED: 03/12/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------------|---------------------|------------------|
| 10/789,492 | 02/26/2004 | Ramez Emile Necola Shehada | 64693-094 | 7995 |

TITLE OF INVENTION: IMPLANTABLE DEVICE WITH SENSORS FOR DIFFERENTIAL MONITORING OF INTERNAL CONDITION

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | YES | \$755 | \$300 | \$0 | \$1055 | 06/12/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION NOT THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further indicated unless corrects maintenance fee notifica | correspondence includir ed below or directed oth tions | g the Patent, advance of serwise in Block 1, by (a | rders and notification of r a) specifying a new corres | naintenance fees v pondence address | vill be and/o | mailed to the current r (b) indicating a sepa | correspondence address as arate "FEE ADDRESS" for |
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| LOS ANGELES | s, CA 90067-3208 | | | | | | (Depositor's name) |
| | | | _ | | | | (Signature) |
| | | | | | | | (Date) |
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| nonprovisional | YES | \$755 | \$300 | \$0 | | \$1055 | 06/12/2009 |
| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | | | | |
| TOTH, K | | 3735 | 600-309000 | | | | |
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| PLEASE NOTE: Uni recordation as set fort (A) NAME OF ASSI | less an assignee is ident h in 37 CFR 3.11. Comp GNEE | ified below, no assignee detion of this form is NO | data will appear on the p T a substitute for filing an (B) RESIDENCE: (CITY | atent. If an assign assignment. and STATE OR C | OUN | TRY) | ocument has been filed for |
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| | s SMALL ENTITY state | s. See 37 CFR 1.27. | b. Applicant is no lon | | | | |
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| Authorized Signature | | | | Date | | | |
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



UNITED STATES PATENT AND TRADEMARK OFFICE

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| 33401 75 | 90 03/12/2009 | | EXAMINER | | | |
| MCDERMOTT V | VILL & EMERY LI | TOTH, KAREN E | | | | |
| 2049 CENTURY PARK EAST | | | ART UNIT | PAPER NUMBER | | |
| 38th Floor | 14 00067 2200 | | 3735 | | | |
| LOS ANGELES, C | A 90067-3208 | TO ACTUS A CAST TUDE OR OLD ORDOOD | | | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 79 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 79 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

Application No. Applicant(s) 10/789 492 NECOLA SHEHADA ET AL. Notice of Allowability Examiner Art Unit KAREN E TOTH 3735 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. This communication is responsive to the remarks and amendment filed 18 February 2009. The allowed claim(s) is/are 62,68,70,75 and 81-87. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance

of Biological Material

9. ☐ Other .

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DETAILED ACTION

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes
and/or additions be unacceptable to applicant, an amendment may be filed as provided
by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be
submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marc Brown on 2 March 2009.

The application has been amended as follows:

In Claim 62, line 9, "displaying data regarding the difference" has been amended to read --displaying data on a display regarding the difference--, in order to provide antecedent basis for the display.

In claim 70, line 12, "representing a device" has been amended to read -representing the device--, in order to maintain continuity in the claim.

In claim 75, line 17, "representing a device" has been amended to read -representing the device-- in order to maintain continuity in the claim.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to anticipate or make obvious the methods of claims 62, 68, 70, and 81-83 including, *inter-alia*, positioning an icon on a display to show the

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position of a sensing device within a body when receiving information from a device having two sensing systems.

The prior art of record fails to anticipate or make obvious the structure of claim 75, including, inter-alia, including a display that is configured to depict an icon representing a device on the display relative to a depiction of the tissue to indicate the position of a device within a body when sensing using an implantable sensor having two sensing systems.

The prior art of record fails to anticipate or make obvious the method of claims 84-87, including, *inter-alia*, determining the condition of a transplanted tissue by using a device having first and second oxygenation sensing systems to measure oxygenation of the transplanted tissue and an adjacent native tissue, where the device is implanted between the transplanted and native tissues, comparing the oxygenation measurements, and determining whether the transplanted tissue is in a "normal" condition based on the comparison.

Armone (US Patent Application Publication 2003/0149346) discloses comparing the absorption values of tissue to determine the location of areas that are diseased. Armone does not disclose using the comparison to determine the current condition of an already known abnormal area.

Masychev (US Patent 6123719) discloses comparing reflectance measurements to a standard to determine the condition of tissue. Masychev does not disclose comparing measured areas to each other to determine tissue condition.

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Mannheimer (US Patent 5218962) discloses comparing oxygenation measurements from multiple regions to each other, but uses the comparison to assess the accuracy of measurements.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/ Examiner, Art Unit 3735

/K. E. T./ Examiner, Art Unit 3735